

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Oleg Iliich Epshtein
Title of Invention : Medicament and method for treating pathological syndrome
Date Filed : January 22, 2005
Serial No. : 10/522,652
Examiner : Dr. Ilia Ouspenski
Art Unit : 1644

DECLARATION UNDER 37 CFR 1.132

I, O. I. Epshtein, Dr. Sc, do hereby declare as follows:

1. My name is Dr. Oleg I. Epstein (aka Epshtein).
2. I am a General Director (CEO) of Materia Medica Holdings, a company that sells a pharmaceutical product named Anaferon in the Russian Federation.
3. Anaferon is covered by the above-identified patent application number 10/522,652. I am an inventor of the '652 application.
4. Anaferon was the only Materia Medica's product covered by the '652 application before January 22, 2005.
5. The '652 application was filed in the United States on January 22, 2005, with acknowledged priority to August 2, 2002 (PCT/RU02/00369).
6. It is my understanding the Examiner now inquired whether any product covered by the claims of the '652 application was on sale or in public use in the United States more than one year before the U.S. filing date of the '652 application.
7. I occupied my present position with Materia Medica Holdings continuously since March 4, 1999. I am well familiar with the operations of Materia Medica Holdings during the time period at issue. At the present time, I have made inquiries to relevant person(s) on Materia Medica's staff.
8. Based on knowledge and belief, I hereby declare that Materia Medica did not offer Anaferon for sale in the United States before August 2, 2002. Out of abundance of caution, based on knowledge and belief, I also hereby declare that Materia Medica did not offer Anaferon for sale in the United States before January 22, 2005.
9. As a person familiar with pharmaceutical products, I am aware that a sale

of a pharmaceutical product in the United States requires approval of the U.S. Food and Drug Administration ("FDA"). I hereby declare that Materia Medica Holding did not apply for FDA approval of Anaferon before January 22, 2005.

10. Based on knowledge and belief, I hereby declare that Materia Medica did not use Anaferon in public in the United States before August 2, 2002. Out of abundance of caution, based on knowledge and belief, I also hereby declare that Materia Medica did not use Anaferon in public in the United States before January 22, 2005.

11. Based on knowledge and belief, I hereby declare that Materia Medica did not allow another person to use Anaferon in the United States without restriction and/or obligation of secrecy before August 2, 2002. Out of abundance of caution, based on knowledge and belief, I also hereby declare that Materia Medica did not allow another person to use Anaferon in the United States without restriction and/or obligation of secrecy before January 22, 2005.

12. Based on knowledge and belief, I hereby declare that I am not aware of any public use of Anaferon in the United States by third parties before August 2, 2002. Out of abundance of caution, based on knowledge and belief, I also hereby declare that I am not aware of any public use of Anaferon in the United States by third parties before January 22, 2005.

All statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment; or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of any patent application issuing thereon.

Dated: February 25, 2009

A handwritten signature in black ink, appearing to read "John Doe".